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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,401	07/01/2003	Manabu Sato	239707US0	9350

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,401

Applicant(s)

SATO ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03/9/2, 10/1, 11/20.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-6 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. In particular, it is not clear what is required in the process.

The steps recited in claims 1 and 3 do not address the preamble as the steps do not relate to the process of immobilizing the enzyme, thus rendering the claims confusing. The step of bringing the immobilized enzyme into contact with the compounds (fatty acid triglyceride, etc.) listed in the claims occurs after the immobilized enzyme is prepared, and seems to correspond to the treatment of the immobilized enzyme. Furthermore, in claims 1 and 3, the final step of esterification is not related to the preparation of the immobilized enzyme. The inclusion of the phrase "wherein the enzyme is used for esterification" renders claims 1 and 3, and dependent claims 2, 4, 5, and 6 indefinite. Thus claims 1-6 are rejected under 35 U.S.C. 112, second paragraph.

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The phrase “adjusting the moisture content of the enzyme” in claim 1 is confusing in that it is unclear how it follows from the previous step of contacting the immobilized enzyme with a fatty acid triglyceride, etc. The adjustment of the moisture content could even suggest drying. Thus claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph.

Finally, the recitation “...in an amount of 20% to 3000% by weight, based on the weight of the carrier...” in claim 3 is indefinite because it is not clear whether the amount corresponds to the weight of the enzyme or the weight of fatty acid, fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof. For examination purposes, the amount of the fatty acid, fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof will be considered to be 20% to 3000% by weight based on the weight of the carrier. Thus claim 3 and dependent claim 4 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. (EP 1,008,647).

EP '647 discloses preparation of an immobilized enzyme for esterification where the enzyme is immobilized on anion exchange resin without drying. The immobilized enzyme is treated with fat and/or oil which are the reaction substrates. See claims 1, 4, 6, and 7 on pages 7 and 8. Example 1 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by treatment with 40 g of soybean oil (page 5, lines 26, 34, and 37). According to the applicants' specification, soybean oil may be used as a fatty acid triglyceride or fatty acid partial glyceride for the treatment of the immobilized enzyme (page 9, last paragraph). In EP '647, the quantity of this oil is 400% by weight based on the weight of the carrier, thus satisfying the weight limitation specified in claim 3. Similarly, Example 3 describes the immobilization of 10 g of lipase on 10 g of anion exchange resin, followed by its treatment with 100 g of aliphatic acid (a fatty acid) derived from soybean oil (pages 5 and 6, in particular, page 5, line 58, and page 6, lines 7-8, 14. Thus the fatty acid amount is 1000% by weight based on the weight of the carrier. Finally, the moisture content of the immobilized enzyme in the '647 invention is given as having a water content of 20% or more by weight (page 4, lines 35-37), thus satisfying the moisture content limitation indicated in claim 3. A holding of anticipation is clearly required.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu et al. (U.S. Pat. No. 6,716,610).

'610 discloses a process where an enzyme for esterification of fats/oils is immobilized on a carrier without drying, followed by the treatment of the immobilized enzyme with the reaction

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substrate. Example 1 satisfies the limitation of the percentage of fatty acid, fatty acid triglyceride, etc. used for the treatment as recited in claim 3 (column 6, lines 4-36 of patent), where soybean oil used for treating the immobilized enzyme constituted 400% by weight, based on the weight of the carrier. Thus '610 discloses claims 1, 3-5, and dependent claims 2 and 6.

The applied reference has a common assignee and two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Shimizu et al. (U.S. 2003/0096383).

The '383 application discloses the same claim limitations as disclosed by the '610 patent. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. (EP 1,008,647) in view of Shimizu et al. (U.S. Pat. No. 6,258,575) and Ruthven (Encyclopedia of Separation Technology, Vol. 2, John Wiley & Sons, Inc., 1997, page 1072).

As discussed above, Shimizu EP '647 discloses a process of treating immobilized enzymes with fat/oil which is the reaction substrate. EP '647 does not expressly disclose the fatty triglyceride, etc. weight range as recited in claim 2.

However, Shimizu '575 discloses that 2000 g of soybean-squeezed oil is passed through a column holding 20 g of immobilized lipase. See Example 2, column 8, lines 25-36. The oil mixture is sent through the column multiple times (column 8, line 36 through column 9, line 7, in particular column 8, lines 59-62). The weight of the carrier, an anion exchange resin, may be estimated by performing a calculation using the dimensions of the column (column 8, lines 28-30) and the density range of exchange resin provided by Ruthven (page 1072, first paragraph under "Density and Specific Gravity"). A density of 700 g/L was used for the estimation, and the mass of resin was determined to be about 48 g. Therefore, the amount of soybean-squeezed

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oil used in Shimizu '575 was about 4100% by weight based on the weight of the carrier. This fits within the range recited in claim 2.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to increase the amount of fatty acid triglyceride, fatty acid partial glyceride, or mixtures thereof used for treating the immobilized enzyme as described in EP '647.

One of ordinary skill in the art would have been motivated to do this because it would have improved exposure of the immobilized enzyme to the reaction substrate. Furthermore, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the result or effect of the process would differ depending on the amount of fat employed. A holding of obviousness is therefore clearly required.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,716,610 or U.S. 2003/0096383.

The '610 patent or '383 application each discloses a process where an enzyme for esterification of fats/oils is immobilized on a carrier without drying, followed by the treatment of the immobilized enzyme with the reaction substrate. As stated above, each satisfies the limitation of the percentage of fatty acid, fatty acid triglyceride, etc. used for the treatment. However, each does not expressly disclose the specific fat amounts as recited in claim 2.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of fatty acid triglyceride, etc. used in the '610 patent or '383 application.

One of ordinary skill in the art would have been motivated to do this since, as stated above, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are directed to an invention not patentably distinct from claims 1-4 of commonly assigned U.S. Pat. No. 6,716,610. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the application claims recite the same basic steps as recited in the patented claims, to the extent that the limitations recited in the claims under examination are contained under the patented claims with the exception of the fat/carrier amounts recited in claims 2 and 3. While the weight ranges of fatty acid, fatty acid triglyceride, etc. as recited in claims 2 and 3 had not been expressly recited in US '610, the selection of the appropriate amount of fat used to treat immobilized enzyme clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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In conclusion, claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,716,610. The claims are directed to an invention not patentably distinct from U.S. '610.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
Assistant Examiner
Art Unit 1651

sef



FRANCISCO PRATS
PRIMARY EXAMINER